

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 04-940-JJF

**REPLY TO TEVA PHARMACEUTICALS USA, INC.'S
OPPOSITION TO THE PROCTER & GAMBLE COMPANY'S
REQUEST FOR ENTRY OF PROPOSED ORDER OF FINAL JUDGMENT**

Plaintiff The Procter & Gamble Company ("P&G") submits this Reply to Teva Pharmaceuticals USA, Inc.'s ("Teva") Opposition to P&G's Proposed Order of Final Judgment. (See D.I. 119).¹ Teva objects to P&G's Proposed Order of Final Judgment ("Proposed Order"), asserting that it is "obviously contrary to law." (D.I. 121 at 1).² Teva's reading of the Proposed Order and the applicable law is incorrect. As discussed below, the Proposed Order is consistent with previous orders entered by this Court, and seeks only the relief to which P&G is entitled under the applicable statutory and regulatory framework. Accordingly, P&G respectfully requests that the Court enter the Proposed Order, with the modification discussed below.

¹ P&G also submitted a Proposed Order of Final Judgment with nearly identical language in a related case, *The Procter & Gamble Company v. Teva Pharmaceuticals USA, Inc.*, No. 08 CV 66 -JJF. (See D.I. 10). Teva opposed the proposed order in Civil Action No. 08-66 on the same grounds as it does here. (See D.I. 12). This Reply, and the arguments made herein, apply equally to Teva's opposition in Civil Action No. 08-66.

² Although P&G gave Teva notice of its Proposed Order before it was filed with the Court, Teva complains that P&G refused Teva's offer to "confer in advance," presumably so that Teva could attempt to modify the terms of the Proposed Order prior to its submission. It is not clear, however, that such a contemplated negotiation between P&G and a generic company would be appropriate. Therefore, out of an abundance of caution, P&G filed the Proposed Order, with notice to Teva, as directed by the Court.

ARGUMENT

I. The Proposed Order Is Not Contrary To Law.

A. The Asserted Claims Of The '122 Patent Are Valid And Enforceable As They Apply To Teva.

P&G's Proposed Order asks the Court to enter judgment that claims 4, 16, and 23 of the '122 patent are valid and enforceable. (D.I. 119). Teva objects to this language, suggesting that this Court cannot enter an order stating that the '122 patent is valid and enforceable.³ Teva's argument is wrong for at least two reasons. As an initial matter, the language in P&G's Proposed Order simply reaffirms what this Court ordered on February 28, 2008 -- that "U.S. Patent No. 5,538,122 is valid and enforceable." (See D.I. 118). In its Opposition, Teva fails to address or even acknowledge the Court's February 28 Order.

Moreover, even apart from the language of the Court's own order, claims 4, 16 and 23 of the '122 patent are, as a matter of law, valid and enforceable as they apply to Teva. At trial, Teva mounted an attack on the validity of the '122 patent. That attack failed.⁴ Consequently, Teva cannot rebut the presumption of validity associated with the asserted claims of the '122 patent. *See, e.g.,* CHISUM ON PATENTS 19.02[3][c] ("Under principles of res judicata and collateral estoppel, a judgment in a patent suit as to issues relating to validity binds the parties to that suit and persons in privity with those parties in any future litigation."); *Tensar Corp v Tenax Corp.*, 1992 WL 443904, at *1315 (D. Md. Oct. 16, 1992) (finding defendants "barred by

³ Of course, P&G acknowledges the truism that patent rights are "negative" rights, such that the Patent Act grants not the right to *practice* the claimed invention, but rather the right to *exclude* others from practicing the invention. However, given the facts of this case and for the reasons set forth herein, that fact does not affect the appropriateness of P&G's Proposed Order.

⁴ In addition, although Teva could have challenged the enforceability of the asserted claims of the '122 patent at trial, it did not do so. As a result, Teva cannot dispute the enforceability of the asserted claims of the '122 patent. *See Golden Blount, Inc v Robert H Peterson Co.*, 365 F.3d 1054, 1062 (Fed. Cir. 2004) (failure to raise an argument that patent is unenforceable at the trial level constitutes a waiver of that argument on appeal).

principles of *res judicata* and collateral estoppel from re-litigating ... any of its defenses of invalidity and unenforceability.”). Therefore, at least with respect to Teva, claims 4, 16 and 23 of the ‘122 patent indisputably are valid and enforceable, and Teva is precluded from arguing otherwise.⁵ *See id.* Since P&G’s Proposed Order applies *only* to Teva, the language proposed by P&G regarding the validity of the ‘122 patent is appropriate.

B. The Proposed Order Appropriately Recognizes Potential Patent Term Extensions and Regulatory Exclusions.

The Proposed Order also states that the effective date of any approval of Teva’s ANDA “shall be modified to a date which is not earlier than the date of expiration of the ‘122 patent, including any extensions and regulatory exclusivities that are granted and not successfully challenged.” (D.I. 119). Teva takes umbrage with this language, and in particular, criticizes the reference to patent term extensions and regulatory exclusivities. For the reasons discussed below, Teva’s various protests fail.

Teva first asserts that P&G’s Proposed Order is beyond the Court’s authority because, according to Teva, the Court cannot “implement ‘regulatory exclusivities.’” (D.I. 121 at 3). However, Teva cites no relevant authority supporting this position. (*See id.* at 3-4). Teva also ignores previous orders entered by this Court which recognize regulatory exclusivities. In fact, P&G’s Proposed Order is consistent with a final judgment order previously entered by this Court enjoining an ANDA applicant from infringing conduct “until such time as the [patent-in-suit] expires, including *any extensions and regulatory exclusivities that are granted and not successfully challenged.*” *See Forest Labs, Inc. v. Ivax Pharms, Inc.*, Civil Action No. 03-891-JJF (November 3, 2006 Judgment Order, attached hereto as Exhibit A) (emphasis added).

⁵ Certainly, in an appropriate litigation, another party can attempt to challenge the validity of the ‘122 patent. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1569-70 (Fed. Cir. 1987) (If a party attacking the validity of a patent fails, the patent remains presumptively valid unless *another challenger* proves invalidity). Teva, however, cannot.

In addition, Teva argues that the Proposed Order is improper because, under the applicable statutory scheme, the '122 patent is not currently subject to a patent term extension. Even assuming Teva is correct, P&G's proposed language is proper. If, for example, the '122 patent became entitled to a patent term extension before its scheduled expiration in December 2013, any injunction against Teva's infringing conduct should apply to that extended term. Failing to acknowledge the potential for a patent term extension in the Court's order on final judgment would harm P&G by limiting its ability to enjoin Teva from infringing conduct during that extended period. However, if P&G does not obtain a patent term extension before expiration of the '122 patent, the inclusion of P&G's proposed language will not impact Teva in any way -- Teva will be enjoined only until the patent expires in 2013.

Finally, Teva complains that the Proposed Order is improper because the Court does not have the authority to enjoin the FDA from approving Teva's ANDA after the '122 patent expires. (*See* D.I. 121 at 4). Again, Teva cites no persuasive legal authority to support this position.⁶ In addition, Teva's argument fails as a practical matter. With respect to pediatric exclusivity pursuant to 21 U.S.C. § 355A(c)(2)(B), Teva admits that, if granted to P&G, the "FDA will automatically delay any ANDA approval for six months after the patent expiration date." (D.I. 121 at 3-4). The Proposed Order therefore simply gives effect to this statutory scheme.⁷

⁶ Teva does not (because it cannot) dispute that this Court has the authority to modify the effective date of its ANDA "to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). *See also Mylan Labs., Inc v Thompson*, 332 F. Supp. 2d 106, 119 (D.D.C. 2004) (finding that district court "properly delayed the effective date of the approval of Mylan's ANDA" after a finding that the patent-in-suit was valid), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004).

⁷ With respect to other potential exclusivities under 21 U.S.C. § 355, the same logic would apply. Under P&G's Proposed Order, the approval date of Teva's ANDA would be after any period of exclusivity granted by the FDA. Again, this is consistent with the statute.

C. The Proposed Order Seeks To Protect Only The Exclusive Rights To Which P&G Is Entitled.

Finally, Teva argues that P&G's Proposed Order "goes too far" and prevents Teva from competing fairly with other generic manufacturers after expiration of the '122 patent. Specifically, Teva complains that the following language in the Proposed Order is improper:

Teva and its successors-in-interest...are hereby enjoined from commercially making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '122 patent...until the later of the expiration of the '122 patent (December 10, 2013) or the expiration of any patent term extensions or any regulatory exclusivities that are granted and not successfully challenged.

(D.I. 119).

The purpose and intent of the Proposed Order is to provide P&G *only* with the rights to which it is entitled under the applicable statutory and regulatory framework. As such, to the extent that P&G's Proposed Order could be interpreted otherwise, P&G agrees that the Proposed Order should be modified to make clear that, after expiration of the '122 patent, Teva's conduct is restricted only to the extent such conduct will violate P&G's exclusive rights under 21 U.S.C. § 355 *et seq.* Accordingly, P&G proposes the following modification to its Proposed Order (shown in italics below):

Teva and its successors-in-interest...are hereby enjoined from commercially making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '122 patent...*until the expiration of the '122 patent (December 10, 2013), including any extensions and regulatory exclusivities that are granted and not successfully challenged.*

This modified language tracks language previously adopted by this Court, *see supra* at 3-4, and makes clear that Teva is only enjoined from commercially making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '122 patent during the life of the patent. After the '122 patent expires, acts such as making,

using and importing risedronate sodium into the United States will no longer “infringe” the ‘122 patent. *See Kearns v Chrysler Corp* , 32 F.3d 1541, 1550 (Fed. Cir. 1994), *cert. denied*, 514 U.S. 1032 (1995) (“Because the rights flowing from a patent exist only for the term of the patent, there can be no infringement once the patent expires.”). Teva’s ability to market and sell risedronate sodium after expiration of the ‘122 patent will be limited by any regulatory exclusivities granted to P&G and not successfully challenged.

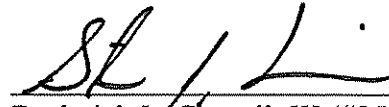
CONCLUSION

For all of these reasons, P&G respectfully requests that the Court enter P&G's Proposed Order of Final Judgment, with the modification discussed above (and reflected in the modified Proposed Order of Final Judgment attached as Exhibit B hereto).

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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**


CERTIFICATE OF SERVICE

I hereby certify that on March 27, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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